00005.001257 PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Examiner: Not Yet Assigned
AKIHIRO UCHIDA, ET AL.	Group Art Unit: Not Yet Assigned
Application No.: 10/528,451	
Filed: March 18, 2005	
For: METHOD FOR STABILIZATION OF DIARYLVINYLENE COMPOUNDS	July 13, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56 and in accordance with the practice under 37 C.F.R. §§ 1.97 and 1.98, the Examiner's attention is respectfully invited to the information discussed below.

In December, 1999, Kyowa Hakko Kogyo Co., Ltd. (assignee of the above-identified application) and/or Kyowa Pharmaceutical, Inc. (a subsidiary of Kyowa Hakko Kogyo Co., Ltd.), commenced clinical trials to ascertain the therapeutic efficacy of compositions comprising solid formulations of xanthine derivatives according to Formula I, stabilized with inorganic compounds or colorants. These clinical trials are controlled by Kyowa Hakko and/or Kyowa Pharmaceuticals, and are still ongoing. In all cases, the

compositions are accounted for, and unused compositions are disposed of or returned to Kyowa Hakko.

None of the subjects in the trials paid for their compositions; rather, the subjects were paid to participate in the trials. Moreover, detailed records are systematically processed and continuously maintained for evaluating efficacy. Similarly, results have been and continue to be monitored by Kyowa Hakko (see representative case report form at Tab 1). In all instances there is an obligation of secrecy owed to Kyowa Hakko by the investigator (see representative nondisclosure agreements at Tab 2) and the subjects were informed the trials were experiments (see representative informed consent memorandum at Tab 3).

Moreover, in all cases there is an implied obligation of secrecy owed by the patients due to the doctor-patient relationship. See *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir. 1984); *McGuire v. Acufex Microsurgical, Inc.*, 868 F.Supp. 388, 397 (D. Mass. 1994).

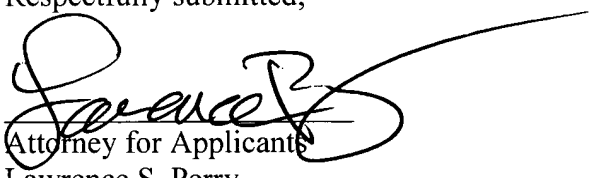
In view of the foregoing, there is no possibility the invention has been used by anyone other than the inventor who has no limitation, restriction or obligation of secrecy to the inventor (c.f., *Grain Proc. Corp. v. American Maize-Prods. Co.*, 840 F.2d 902, 906 (Fed. Cir. 1988)), nor is it possible, given the totality of the circumstances, that the public could reasonably come to believe the solid formulations were freely available (c.f., *Tone Bros. v. Sysco Corp.*, 28 F.3d 1192, 1198 (Fed. Cir. 1994), *cert. denied*, 514 U.S. 1015 (1995)).

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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